JUL 29 2005 K041893 1 of 3

SUMMARY OF SAFETY AND EFFECTIVENESS

THIS 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION IS BEING SUBMITTED IN ACCORDANCE WITH THE REQUIREMENTS OF SMDA 1990 AND 21 CFR 807.92.

1. SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON, AND DATE SUMMARY PREPARED

a. Applicant:
IntraLase Corp.
3 Morgan
Irvine, CA 92618

b. Contact Person:
Judy F. Gordon, D.V.M.
ClinReg Consulting Services, Inc.
2 Delphinus
Irvine, CA 92603

c. Date Summary Prepared:
May 9, 2005

2. NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME:

a. Trade/Proprietary Name:
INTRALASE FS Laser

b. Classification Name:
Laser

3. IDENTIFICATION OF THE PREDICATE DEVICE OR LEGALLY MARKETED DEVICE OR DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS BEING CLAIMED:

510(k)	Applicant	Name of Device	Date Cleared
K981063	Laser Center Development Corporation	Automated Corneal Trephine	June 23, 1998
K013151	BKG Ophthalmics USA, Inc.	ASMOTOM Automated Corneal Trephine	December 14, 2001
K002890	IntraLase Corporation	Femtosecond Laser Keratome	August 9, 2001

4. **A DESCRIPTION OF THE DEVICE THAT IS THE SUBJECT OF THE 510(K), INCLUDING EXPLANATION OF HOW THE DEVICE FUNCTIONS, BASIC SCIENTIFIC CONCEPTS, SIGNIFICANT PHYSICAL AND PERFORMANCE CHARACTERISTICS (DESIGN, MATERIAL, PHYSICAL PROPERTIES):**

The INTRALASE FS Laser is a precision ophthalmic surgical laser designed for use in performing lamellar and full thickness or penetrating corneal resections. The cutting action of the *INTRALASE FS* Laser is achieved through precise individual micro-photodisruptions of tissue, created by tightly focused ultrashort pulses which are delivered through a disposable applanation lens while fixating the eye under very low vacuum.

5. **STATEMENT OF INTENDED USE:**

The INTRALASE® FS Laser is an ophthalmic surgical laser with the following indications for use:

- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments
- In lamellar keratoplasty and corneal harvesting
- In keratomileusis *in situ* for the correction of myopia
- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea
- In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty and in the creation of a penetrating cut/incision for penetrating keratoplasty.

These additional indications for use are identical to those of the predicate devices.

6. **STATEMENT OF HOW THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARE TO THOSE OF THE PREDICATE OR LEGALLY MARKETED DEVICE.**

The technological characteristics of the INTRALASE FS Laser have already been cleared under K002890 for corneal harvesting. The design, materials, and

characteristics of the laser keratome are the same irrespective of the indication for use.

7. **BRIEF SUMMARY OF NONCLINICAL TESTS AND RESULTS:**

The INTRALASE FS Laser has undergone testing in accordance with applicable safety standards. In addition, the INTRALASE FS was found to perform equivalently to the predicate devices with respect to the creation of partial or full thickness corneal resections in the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty and in the creation of a penetrating cut/incision for penetrating keratoplasty. Thus, the INTRALASE FS Laser and the predicate device have similar safety, effectiveness and performance profiles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 2005

IntraLase Corporation
c/o Judy F. Gordon, D.V.M.
Regulatory Consultant to IntraLase
ClingReg Consulting Services Inc.
2 Delphinus
Irvine, California 92603

Re: K041893
Trade/Device Name: INTRALASE FS Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: July 6, 2005
Received: July 7, 2005

Dear Dr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041893

Device Name: INTRALASE FS Laser

Indications for Use:

The INTRALASE® FS Laser is an ophthalmic surgical laser with the following indications for use:

- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments
- In lamellar keratoplasty and corneal harvesting
- In keratomileusis *in situ* for the correction of myopia
- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea
- In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty and in the creation of a penetrating cut/incision for penetrating keratoplasty.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K041893